

Applicant: Kurt-Reiner Geiss
Application No.: 10/665,394
Examiner: Snigdha Maewall

Remarks

Claims 1-13 have been cancelled. New claims 14-36 have been added. Claims 14-36 are presented for the Examiner's review and consideration. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Interview

Applicant thanks the Examiner and her supervisor, Dr. Gollamudi Kishore, for courtesies extended to Applicant's representatives, Paul Bianco and Katharine Davis Wong, during the telephone interview of December 10, 2008. The amendments and remarks presented herein reflect those discussed during the interview.

Amendments to the Specification

No new matter has been added by the amendments to the title made herein. The title has been amended herein only to correspond with the claims as currently pending.

Amendments to the Claims

No new matter has been added by the addition of new claims 14, 16, 18-20, 23, 25, 27-32, and 35. The subject matter of these new claims is supported by claims 1-13 as originally filed. New claim 14 incorporates the subject matter of cancelled claim 1; new claim 16 cancelled claim 2; new claim 19 cancelled claim 4; new claim 20 cancelled claim 3; new claim 23 cancelled claim 5; new claim 25 cancelled claim 6; new claim 28 cancelled claim 10; new claim 29 cancelled claim 11; new claim 30 cancelled claim 9; new claim 31 cancelled claim 13; new claim 32 cancelled claim 7; and new claims 18, 27, and 35 cancelled claim 8. New claims 18, 27, and 35 are further supported by paragraph [0023] of the published application, US 2004/0120985 A1

Applicant: Kurt-Reiner Geiss
Application No.: 10/665,394
Examiner: Snigdha Maewall

(hereinafter referred to as “published application”), which indicates that the claimed food has a protein content of at least 10 wt %.

No new matter has been added by the addition of new claims 15, 24, and 33. These claims were added to clarify a particular improvement in cognitive functional capacity, namely increases in memory, concentration, and attentiveness in the consumer of the described foods and bars. This subject matter is supported by the specification as originally filed; for example, at paragraph [0012] of the published application and claims 3 and 12 as originally filed.

No new matter has been added by the addition of new claims 17, 26, and 34. These claims were added to indicate that the carbohydrates included in the described foods and bars are simple carbohydrates that are quickly digestible, such as glucose, fructose, sucrose, and/or combinations thereof. This subject matter is supported by the specification as originally filed; for example, at paragraphs [0020] and [0052] of the published application.

No new matter has been added by the addition of new claim 21. This claim was added to indicate that the improvement of cognitive function obtained by consuming the described foods and bars can be a short-term improvement. This subject matter is supported by the specification as originally filed; for example, at paragraphs [0022] and [0053] of the published application.

No new matter has been added by the addition of new claim 22. This claim was added to indicate that when the foods or bars are consumed regularly, the improvement of cognitive function can be a long-term improvement. This subject matter is supported by the specification as originally filed; for example, at paragraphs [0025] and [0053] of the published application.

No new matter has been added by the addition of new claim 36. This claim was added to specify specific amounts of phosphatidyl serine and carbohydrates included within the range of amounts recited in parent claim 23; 200mg phosphatidyl serine and 18g carbohydrates. This claim was also added for the same reasons as claims 15, 24, and 33 were added; to clarify a particular improvement in cognitive functional capacity, namely increases in memory, concentration, and attentiveness in the consumer of the described food bar. This subject matter is supported by the specification as originally filed; for example, at paragraph [0012] of the published application and claims 3 and 12 as originally filed.

Applicant: Kurt-Reiner Geiss
Application No.: 10/665,394
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Rejection under 35 U.S.C. §103(a)

Claims 1-13 were rejected under 35 U.S.C. §103(a), as being unpatentable over Buchholz et al. (U.S. Patent 6,514,973 B1; hereinafter “Buchholz”) in view of Lang et al. (U.S. Patent Application Publication 2003/0161861 A1; hereinafter “Lang”). Claims 1-13 have been cancelled. New claims 14, 16, 18-20, 23, 25, 27-32, and 35 correspond to the cancelled claims. For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

It is noted that the references are described individually only to clarify what each reference teaches and not to argue each reference separately.

Buchholz

Buchholz discloses compositions for the treatment and prevention of transmethylation disorders, particularly for the treatment of neurological and pathopsychological diseases. *See* column 1, lines 6-8. The compositions contain three active ingredients; component A: one or more phosphatidyl serines, component B: one or more methyl transporters, and component C: one or more compounds selected from methyl and methylene donors, provided that the phosphatidyl serines and compounds with methyl transporting properties do not form part of component C. *See* abstract and column 1, line 61 to column 2, line 7. These compositions are useful for reducing elevated levels of homocysteine found in transmethylation disorders. *See* column 1, line 37 to column 2, line 12.

Buchholz discloses, as background, a previous study demonstrating the long-term benefits of phosphatidyl serine supplementation. In this study, it was documented that oral supplementation with 200-300mg of phosphatidyl serines per day for 2 to 6 months improves brain metabolism and benefits cognitive functions such as memory, thinking, learning, and the ability to concentrate, especially in aging people and in patients with certain neurological and pathopsychological conditions. *See* column 2, lines 22-27. However, in the actual composition

disclosed by Buchholz, phosphatidyl serine was added only in an amount of 50mg. *See Example 1.*

Buchholz does not teach the role of carbohydrates in improving cognitive function of the brain. Further, Buchholz does not discuss any connection or relationship between phosphatidyl serine and glucose intake in the brain, other than to mention that it has been assumed that phosphatidyl serines are able to stimulate glucose metabolism in the brain. *See column 2, lines 32-37.*

The compositions disclosed by Buchholz are suitable as a food or food supplement and are prepared by combining the active ingredients, components A-C, with edible “nutritional substances”, including carbohydrates. Thus, Buchholz adds carbohydrates only to make the phosphatidyl serine more palatable for consumption, and therefore, considers the “nutritional substances”, such as carbohydrates, inactive ingredients. *See column 5, lines 40-49 and column 6, lines 9-12.*

Lang

Lang discloses the use of a cereal product such as a biscuit or cracker having a slowly digestible starch content relative to the total starch content higher than about 12 wt %, preferably higher than about 20 wt %, to improve cognitive performances, in particular memory retention, attention, concentration, vigilance and/or mental well-being in people, and particularly in a child and an adolescent. *See abstract.*

In the background material, Lang discusses conflicting experimental results regarding the role of glucose in cognitive functions, some studies show glucose improves these functions, and others show glucose has no role in these processes. *See paragraphs [0015] and [0016].* In actual results, Lang shows that the regulation of the glycemic index alone was insufficient to increase cognitive performances and demonstrates that certain cereal products significantly improve cognitive performance, by virtue of the choice of appropriate proportions between slowly

digestible starch and the total starch present in the product. *See paragraph [0017].* Lang does not disclose or suggest the use of phosphatidyl serine in the biscuit composition.

In experimental Example 1, Lang compares learning and locomotive activity in two groups of rats, one of which consumes Lang's biscuits and the other ready-to-eat cereals. The rats which consumed biscuits exhibited learning results which were significantly superior to those of the rats which consumed ready-to-eat cereals. Additionally, in locomotive activity, the rats which consumed a biscuit-based breakfast were calm, whereas the rats which consumed a breakfast based on ready-to-eat cereals were more active and showed signs of distress (more passages in the central compartment, this indicating higher distress, since the behavior of crossing a room along the diagonal rather than along the walls is unusual in rats). Lang concludes that the bioavailability of starch makes it possible to explain the differences in results in these experiments. As such, Lang discloses improving cognitive performance by consuming a food product combining certain proportions of slowly digestible starch with respect to the total starch of the food product.

Instant Invention

Generally, the present invention provides a food product for increasing cognitive functional capacity, particularly a food product for increasing memory, concentration, and attentiveness in the consumer of the food. *See abstract and paragraph [0012] of the published application, and claims 3 and 12 as originally filed.* This food item, preferably a bar of chocolate, has a phosphatidyl serine content of 100-300mg and a relatively high carbohydrate content.

The starting point of the present invention is the discovery that, in older individuals, the intake of 100-300mg of phosphatidyl serine per day can lead to an improvement of the cognitive functional capacity, in particular the memory and learning capacity, and to an increase in the powers of concentration and attentiveness. *See paragraphs [0010] and [0012].*

This claimed food product or bar has a relatively high content of simple carbohydrates, such as glucose, fructose, sucrose, and/or combinations thereof. By specifically combining the intake

of carbohydrates and phosphatidyl serine, the glucose intake, and thus the glucose content in the brain cells, is markedly increased. In the short term, this makes possible an especially marked increase in the cognitive functional capacity. Preferably, the minimum quantity of carbohydrates is 15g combined with 100-300mg of phosphatidyl serine. *See paragraph [0020].*

Furthermore, when consumed regularly, three to four bars per week suffice to sustain a long-term increase of cognitive functional capacity. *See paragraphs [0025] and [0053].*

Thus, the present invention is a food product or bar that specifically combines the intake of phosphatidyl serine with the intake of carbohydrates. Applicant found this combination to improve cognitive function both shortly after consumption (short-term improvement) and over time (long-term improvement). Neither this combination nor the positive effects on cognitive functional capacity resulting from consumption of foods containing this combination are suggested in the prior art.

Argument

The Examiner states that although Buchholz teaches that phosphatidyl serine stimulates glucose metabolism in the brain, Buchholz does not specifically teach the role of carbohydrates in improving brain function. The Examiner further states that Lang teaches food products containing carbohydrates, such as starch, which improve cognitive performance. The Examiner thus concludes that it would have been obvious to one of ordinary skill in the art at the time that the invention was made to incorporate carbohydrates into the composition of Buchholz, since Lang teaches that carbohydrates improve cognitive function.

Applicant respectfully disagrees. One of ordinary skill in the art looking to change and/or improve performance of the composition of Buchholz would not look to the teachings of Lang. Buchholz appears to include phosphatidyl serine in the composition because phosphatidyl serine makes pro-homeostatic contributions and provides a wide range of support to brain function. Further, Buchholz notes phosphatidyl serine is assumed to stimulate glucose metabolism in the brain and to increase the number of neurotransmitter receptor sites. *See column 2, lines 32-37.*

Buchholz does not disclose any other connection or relationship between phosphatidyl serine and glucose intake in the brain and mentions simple carbohydrates, such as glucose, only as a nutritional substance, and thus, an inactive ingredient in the described composition. *See* column 5, lines 45-62 and column 6, lines 9-12. Thus, Buchholz does not suggest that glucose, or any other carbohydrate, would have any effect on the function of the described composition, or would interact with phosphatidyl serine to improve cognitive function.

Lang teaches a food product, having a higher content of slowly digestible starch relative to the total starch content, which provides long-term improvements in cognitive function. *See* abstract and paragraph [0075]. Lang discloses conflicting results regarding levels of glucose and improvement of cognitive functions. Lang also shows that regulation of glycemic index alone is insufficient to increase cognitive functions. *See* paragraphs [0015]–[0017]. Lang does not suggest any other materials which may be combined with starch to influence or improve cognitive function.

Particularly, Lang teaches a specific ratio of slowly digestible starch to total starch in the food. It is this balanced ratio that enables the food product to improve cognitive function over long periods of time. *See* paragraph [0017]. Lang does not suggest combining starch with any other material. Furthermore, the addition of phosphatidyl serine or other material might disrupt the balanced combination of slowly digestible starch to total starch, and thus, possibly diminish the effectiveness of the food. In effect, Lang actually discourages combinations of starch and other materials.

In contrast to the compositions of Buchholz and Lang, the claimed food product, including a combination of phosphatidyl serine and carbohydrates, provides measurable improvements in cognitive functional capacity upon consumption. The effect of this combination of phosphatidyl serine and carbohydrates on concentration, memory, and attention is demonstrated in the first experimental example provided in the attached Declaration of the inventor, Dr. Kurt-Reiner Geiss. In this experiment, study volunteers were evaluated pre-supplementation and after twelve weeks of consuming one IQPLUS Brain Bar per day for the first two weeks, followed by half an

Applicant: Kurt-Reiner Geiss
Application No.: 10/665,394
Examiner: Snigdha Maewall

IQPLUS Brain Bar for the next ten weeks. The IQPLUS Brain Bar contains 200mg of phosphatidyl serine and 20g of carbohydrates. After the second evaluation, the volunteers stopped consuming the IQPLUS Brain Bars and were re-evaluated during week twenty-four. The combination of phosphatidyl serine and carbohydrates in the form of the IQPLUS Brain Bar resulted in improvements in all categories of concentration, attention, and memory tested (results after twelve weeks of IQPLUS Brain Bar consumption in comparison to starting values). A comparison of results after twelve weeks consumption with results after an additional twelve weeks without any further supplementation showed a decline in all categories at week twenty-four. The results regarding concentration and attention are shown in Table 2 and results regarding memory and attention are shown in Table 3 (experimental example one).

A plethora of bars and drinks high in carbohydrate content are known in the art and are consumed to provide quick energy. Likewise, phosphatidyl serine supplements are known in the art and are consumed to provide improvements in cognitive functions. Carbohydrates have been added to the phosphatidyl serine supplements to make them more palatable for consumption. However, no one has added carbohydrates to phosphatidyl serine with the purpose or expectation that they would interact to actively improve cognitive functions, such as memory, concentration, learning, and attentiveness. The instant inventor has discovered this unexpected functional relationship between phosphatidyl serine and simple carbohydrates. Such an unexpected functional relationship demonstrates that the claimed food products and bars are not obvious in view of the cited art (Buchholz and Lang) or any other prior art.

Evidence of a greater than expected result may be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (*i.e.* demonstrating “synergism”). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). MPEP 716.02(a).

Applicant demonstrated a greater than expected increase in cognitive functional capacity after consumption of a combination of phosphatidyl serine and simple carbohydrates over consumption of phosphatidyl serine or simple carbohydrates alone (shown in the second

Applicant: Kurt-Reiner Geiss
Application No.: 10/665,394
Examiner: Snigdha Maewall

experimental example provided in the attached Declaration of Dr. Kurt-Reiner Geiss). In this experiment, the influence of the claimed food product on cognition during golfing (tee-off accuracy) was tested and compared to the influence of the ingredients (phosphatidyl serine and simple carbohydrates) alone. Cognition refers to the processing of information and applying the information processed. The golf swing is a complex motion and, especially at tee-off, creates high levels of tension with potential negative effects on cognitive function, including memory, attentiveness, and concentration. Memory and focus (attentiveness) play a major role during the golf swing as the golfer has to memorize the perfect swing and recall the motion while trying to hit the ball to the best of his/her ability and all the while staying focused to avoid mistakes. Golfers participating in the clinical study first performed a standardized ten minute warm-up that did not include practice shots. After the warm-up, the golfers teed-off twenty times in fifteen second intervals and were asked to hit a target at a distance of 135 meters. The quality of the ball flight was recorded immediately after the ball hit the ground after tee-off. A good ball flight (hit) was defined as “correct flight”, “draw”, or “fade”, whereas all other ball flights were recorded as a miss. A schematic representation of ball flight is shown in Figure 2 of example two. After the first test, the golfers consumed a combination of 200mg phosphatidyl serine and 20g of simple carbohydrates (as IQPLUS Golf Bar, n=10), 20g of simple carbohydrates (as a nutrition bar, n=10), or 200mg of phosphatidyl serine (as soft gel capsules, n=2) for six weeks. After six weeks, the ball flight test was repeated. It was found that the combination of phosphatidyl serine and simple carbohydrates resulted in a significant improvement of good ball flights, whereas simple carbohydrate or phosphatidyl serine consumption did not improve performance. See “results” section of experimental example two for pre-test and post-test statistical comparisons. The improvements are known to be due to mental aspects, in light of the conditions of the experiment, *i.e.* the physical, mental, and golf-specific training habits of each individual participant remained unchanged during the supplementation phase. Thus, Applicant has provided evidence of a synergistic effect on cognitive functional capacity from the combination of phosphatidyl serine and simple carbohydrates over the effect of each ingredient alone (*i.e.* phosphatidyl serine alone and simple carbohydrates alone).

Applicant: Kurt-Reiner Geiss
Application No.: 10/665,394
Examiner: Snigdha Maewall

The prior art does not teach or suggest a food product for improving cognitive functional capacity of the consumer of the food product comprising a minimum of 100mg to about 300mg of phosphatidyl serine and a minimum of 15g of carbohydrates, wherein glucose intake into the brain cells of the consumer is improved by consuming the food bar. Thus, even if one of ordinary skill in the art were to combine the teachings of Buchholz and Lang, one would not arrive at the food product as currently claimed. Neither these references nor other prior art teach the unexpected beneficial results of the combination of at least 100mg phosphatidyl serine combined in food with a relatively high content of carbohydrates, particularly simple carbohydrates. Furthermore, the prior art does not teach a food, which after consumption, produces a marked increase in glucose uptake in the brain with concomitant beneficial results in cognitive function. One would not have any reason or motivation for incorporating carbohydrates into the composition of Buchholz because neither Lang nor other prior art suggests that carbohydrates combined with phosphatidyl serine can increase glucose uptake in the brain to improve cognitive functional capacity.

Accordingly, Applicant respectfully submits that independent claims 14, 23, and 32 (correspond to cancelled claims 1, 5, and 7) are patentable over Buchholz in view of Lang. As claims 15-22 depend from claim 14, claims 24-31 depend from claim 23, and claims 33-35 depend from claim 32, these dependent claims necessarily include all the elements of their base claims. Thus, Applicant respectfully submits that the dependent claims are allowable over Buchholz in view of Lang at least for the same reasons.

In light of the foregoing arguments and attached Declaration under 37 C.F.R. § 1.132, Applicant requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

Applicant: Kurt-Reiner Geiss
Application No.: 10/665,394
Examiner: Snigdha Maewall

Conclusion

In light of the foregoing amendments, remarks, and attached Declaration under 37 C.F.R. § 1.132 this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a request for continued examination pursuant to section 1.17(e) in the amount of \$810, the fee for a one month extension of time pursuant to Section 1.17(a)(1) in the amount of \$130, and the fee for extra claims pursuant to 1.16(i) in the amount of \$156 are believed to be due and are being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7390-X03-018).

Respectfully submitted,

/Katharine F. Davis Wong/

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